Patent Docket P1363R1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Application of<br>Deborah Ann Ansaldi<br>Serial No.: 09/320,100<br>Filed: 26 MAY 1999<br>For: SEPARATION OF POLYPEPTIDE MONOMERS | Group Art Unit: 1642<br>Examiner: Anne Holleran<br><br>CERTIFICATE OF MAILING<br>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Alexandria, VA 22313 on<br>July 22, 2003<br>Ann Savelli<br>Ann Savelli |

**COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE**

Mail Stop ISSUE FEE
Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

A Notice of Allowance was mailed for pending claims 1-15 for the above indicated application on May 28, 2003, including a Statement of Reasons for Allowance. In this Statement, the Examiner indicated that the Chaudhary reference (Chaudhary *et al.*, Nature, 339: 394-397 (1989)) teaches a method for the separation of scFv from aggregates, and the method of Chaudhary includes the additional step of gel filtration (see page 395, 1st column), whereas the claimed methods exclude additional purification steps (the claimed methods consist essentially of ion-exchange chromatography). Thus, the Examiner concluded that the claimed methods do not read on the methods of Chaudhary.

Applicants wish to note for the record that the instantly claimed method is sufficiently distinguished over Chaudhury in that the latter does not teach or suggest purification of monomers from their own dimers and/or multimers, but rather from aggregates (see p. 395, first column, where it indicates that high-molecular weight aggregates were eluted at higher ionic strength, i.e., fractions 42-50 of Fig. 2a). Thus, the renatured protein applied to the column in Chaudhary contains monomers and aggregates of the

desired protein, but Chaudhary is silent as to the presence of dimers and/or multimers thereof as required by the instant claims. The fact that further purification of the monomer was carried out on a gel filtration column is irrelevant, because Chaudhury is not using ion-exchange chromatography to purify monomers from dimers and/or multimers as currently claimed. The claimed method does not exclude additional purification steps, but rather the instant method consists essentially of the ion-exchange step because that is the step that removes the dimers and multimers from the monomer; other steps are not required to accomplish this task.

Respectfully submitted,
GENENTECH, INC.

Date: July 22, 2003

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